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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/503,089	02/11/2000	Amanda J. Patel	1030-R-00	6089

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	17

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/503,089	Patel et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-16, 18-20, 22, 23, and 25* is/are pending in the application.

4a) Of the above, claim(s) *1-12* is/are withdrawn from consideration.

5) ☒ Claim(s) *16, 18-20, 22, 23, and 25* is/are allowed.

6) ☒ Claim(s) *13-15* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2002 has been entered.

2. Claims 1-12 remain withdrawn from consideration. Claims 13-16, 18-20, 22, 23 and 25 are under consideration.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

4. The rejection of claims 13, 15, 16, 18, and 20 under 35 U.S.C. 103(a) as being unpatentable over Franks and Lieb (Nature, 1994, Vol. 367, pp. 607-614) in view of Fink (EMBO, 1996, Vol. 15, pp. 6854-6862) is withdrawn in light of applicants arguments.

5. The rejection of claims 13, 14, 22 and 25 under 35 U.S.C. 103(a) as being unpatentable over Franks and Lieb (Nature, 1994, Vol. 367, pp. 607-614) in view of Duprat et al (EMBO, 1997, Vol. 16, pp. 5464-5471) is withdrawn in light of applicants arguments.

6. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for TREK-1 as SEQ ID NO:2 and 4 and TASK as SEQ ID NO:5, does not reasonably provide enablement for variants of TREK1 or TASK. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

Claim 13 is drawn to a method of identifying substances having anesthetic properties , wherein said substances produce a reversible state of consciousness with concurrent amnesia and analgesia in a mammal upon inhalation comprising contacting said substance with TREK-1 or TASK mammalian potassium transport proteins wherein said TREK or TRAK protein exhibits outward-going potassium rectification; and determining the potassium transport activity of said TREK or TASK proteins wherein an activation of potassium transport is indicative of said substance having anesthetic properties. Claim 14 embodies the method of claim 13 wherein said potassium transport protein is TASK. Claim 15 embodies the method of claim 13 wherein said potassium transport protein is TREK1.

The specification teaches human TREK-1 (SEQ ID NO:2), mouse TREK-1 (SEQ ID NO:4) and murine TASK (SEQ ID NO:5) as novel mammalian outward K+ rectifiers, which are potassium channels activated in the presence of anesthesia, and thus a protein target for the screening of compounds which can act as general anesthetics in mammals. The specification states on page 6, line 21, that the molecular sequence of TREK-1 may be the human TREK as shown in SEQ ID NO:2, or an amino acid sequence that is substantially identical to SEQ ID NO:2. By substantially identical it is understood that amino acid substitutions may be made such that the overall confirmation of the potassium transport protein is not significantly altered. The specification states that TASK my be derived from any mammalian source such as rat mouse or human. The specification does not provide a definitions for TASK that would limit it to a single SEQ ID NO or a specific function. When given the broadest reasonable interpretation, method claims 13-15 encompass variants of both TREK-1 and TASK which have not been disclosed in the specification. Although the specification contemplates variants of TREK1 that retain potassium transport activity, the specification has not taught how to modify the claimed variants of TREK and TASK in order to preserve the functional properties of the disclosed TREK and TASK. It is noted that the specification does not limit TASK derived from mammalian sources other than the mouse, to retaining potassium transport activity. It is well known in the alt that

protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, as disclosed by Burgess et al. (Journal of Cell Biology, 1990, Vol. 111, pp. 2129-2138, cited in a previous Office action) replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein.. In experiments with transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen.(Lazar et al, Molecular and Cellular Biology, 1988, Vol. 8, pp.1247-1252, cited in a previous Office action). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. In addition, Fink et al (EMBO, 1996, Vol. 15, pp. 6854-6862, cited in a previous Office action) teach that although potassium channel proteins TWIK-1 and TREK-1 have structural similarity with respect to pore-forming domains and transmembrane domains, this does not translate to functional similarity as TWIK-1 is inwardly rectifying and TREK-1 is outwardly rectifying. Clearly, it could not be predicted that a variant of SEQ ID NO:2, 4 or 5 would function in a method of screening for compounds which would induce general anesthesia. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use variants of TREK-1 or TASK. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

7. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The embodiments of the claims are recited above. The claims are broadly drawn to encompass methods reliant upon TREK-1 and TASK. The specification teaches

human TREK-1 (SEQ ID NO:2), mouse TREK-1 (SEQ ID NO:4) and murine TASK (SEQ ID NO:5). The specification states on page 6, line 21, that the molecular sequence of TREK-1 may be the human TREK as shown in SEQ ID NO:2, or an amino acid sequence that is substantially identical to SEQ ID NO:2. By substantially identical it is understood that amino acid substitutions may be made such that the overall confirmation of the potassium transport protein is not significantly altered. The specification states that TASK my be derived from any mammalian source such as rat mouse or human. The specification does not provide a definitions for TASK that would limit it to a single SEQ ID NO or a specific function. When given the broadest reasonable interpretation, method claims 13-15 encompass variants of both TREK-1 and TASK which have not been disclosed in the specification. Thus the claimed methods are dependent upon a genus of TREK-1 proteins and a genus of TASK proteins. The specification or claims does not place any limit on the number of amino acid substitutions, insertions or deletions that would be encompassed in a TREK-1 or TASK protein variant, and neither the specification nor claims limit the TASK variant in terms of a specific function. Although the specification states that these types of changes are routinely done in the art, neither the specification nor claims provide any guidance as to what changes can be made. Structural features and functional attributes that could distinguish proteins in the TASK genus from other proteins are missing from the disclosure. Structural features of TREK-1 proteins that would serve to identify members of the genus are also missing from the disclosure. The general knowledge and skill in the art doe not supplement the omitted description because specific, not general guidance is hat is needed. Since the disclosure fails to describe the common structural attributes of the TREK-1 genus, and the common structural and functional attributes of the TASK genus , and because the genuses are highly variant, SEQ ID NO: 2 and 4 and SEQ ID NO:5 are insufficient to describe the claimed genuses.

8. Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-15 are rendered vague and indefinite in the recitation of TREK-1 and TASK as the only means of identifying the proteins on which the method claims depend. The use of laboratory designations only to identify a particular protein renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct proteins and peptides. Amendment of the claims to include a sequence identifier is required, because sequence identifiers are unique identifiers which unambiguously define a given protein.

9. All other rejections and objections as set forth in Paper No. 12 are withdrawn.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
February 10, 2003